K123135
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JAN 2 8 2013

Arstasis

SECTION 2. 510(k) SUMMARY

Sponsor/Submitter:	Arstasis, Inc. 740 Bay Road
Contact Person:	Debra Cogan Director, Quality Assurance, Regulatory & Clinical Affairs Phone: (650) 261-8073
Date of Submission:	October 4, 2012
Device Trade Name:	AXERA 2 Access System
Common Name:	Catheter Introducer
Device Classification:	Class II
Regulation Number:	21 CFR 870.1340
Classification Name:	Catheter Introducer
Product Code:	DYB
Predicate Device:	AXERA Access System (K121521)
Device Description:	The AXERA 2 is a device that is comprised of a latchwire, anchor mechanism, shaft and handle with control features.
Indications for Use:	The AXERA Access System is intended to provide access for the percutaneous introduction of devices into the peripheral vasculature and to promote hemostasis at the arteriotomy site as an adjunct to manual compression. AXERA is indicated for use in patients undergoing diagnostic femoral artery catheterization procedures using 5F or 6F introducer sheaths.
Technological Characteristics	The AXERA 2 Access Device is designed to create a shallow access path through the arterial wall for the guidewire to enter the vessel lumen.
Performance Data	Device is unchanged for the predicate device. The predicate device met all performance testing acceptance criteria.

Summary of Substantial Equivalence:

There are no changes to the Indications for Use. The clinical section of the Instructions for Use was amended to include a summary of the RECITAL study results. The clinical summary includes data related to patient safety, device performance and efficacy, including time to hemostasis, time to ambulation, time to sit up 45 degrees, time to discharge eligibility and actual discharge.

Device is unchanged for the AXERA 2 Access System. Bench Testing performed for the predicate device is applicable and was not repeated for the subject AXERA 2 Access Device. All acceptance criteria for bench testing performed for the predicate device were met and test results demonstrated that the predicate device met performance requirements for its intended use. No new issues of safety or effectiveness have been raised when compared to the predicate device.

Prior bench testing of the AXERA 2 device included device functionality, deployment forces (heel, needle, plunger), release forces (heel), flex conditioning (latchwire), resistance of latchwire to damage by flexing, tensile strength of multiple joints (latchwire, anchor, heel, plunger, plunger tube, needle), compressive strength (handle/anchor, plunger lockout), and torque loading (handle/anchor), corrosion resistance testing, biocompatibility testing, preliminary animal studies (non-GLP) and cadaver assessments, as well as clinical investigations.[1] Multiple clinical evaluations were conducted. The short term safety and clinical performance of the device were established. The long term safety, as well as the ability to access and re-access, was retrospectively studied in a smaller cohort of patients.

In summary, the cumulative data provided herein demonstrates that the AXERA 2 Access System is substantially equivalent to its predicate in providing access to the arterial lumen and facilitating the introduction and placement of devices into the peripheral vasculature and achievement of hemostasis.

[1] The preliminary Animal Studies and Cadaver Assessments were conducted using prototypes of a similar design and configuration.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Arstasis, Inc.
c/o Ms. Debra Cogan
Director, Quality Assurance, Regulatory & Clinical Affairs
740 Bay Road
Redwood City, CA 94063

JAN 2 8 2013

Re: K123135
Trade Name: AXERA 2 Access System
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: December 19, 2012
Received: December 20, 2012

Dear Ms. Cogan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Matthew G. Hillebrenner

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K123135

Arstasis

Traditional 510(k)

SECTION 1. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K123135

Trade Name: AXERA 2 Access System

Common Name: Catheter Introducer

Indications For Use: The AXERA Access System is intended to provide access for the percutaneous introduction of devices into the peripheral vasculature and to promote hemostasis at the arteriotomy site as an adjunct to manual compression. AXERA is indicated for use in patients undergoing diagnostic femoral artery catheterization procedures using 5F or 6F introducer sheaths.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K123135